K-M graphs. **CONCLUSIONS:** Due to very limited availability of trials with robust endpoints and long-term follow-up, alternative options for establishing comparative efficacy must be used for decision making in relapsed or refractory MCL. These alternatives include implementing comparisons of single-arm trial data without adjustment (i.e., via naïve comparison) or methods such as match-adjusted indirect comparison (MAIC) to derive comparative estimates. MAIC is a relatively novel method and may be difficult to implement given the heterogeneity in trial designs and patient-level characteristics in MCL trials. The scarcity of K-M data to inform PFS and OS of certain comparators further limits the comparisons that can be made through modeling.

PCN11

THE EFFICACY OF CURRENT TREATMENT OPTIONS FOR METASTATIC CERVICAL CANCER

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OBJECTIVES: The prognosis of patients with metastatic cervical cancer (CC) remains poor, and treatment options are limited, with no single agent or combination of agents recognised as standard of care; cisplatin/paclitaxel is the therapy most cited by guidelines. This study aimed to assess the efficacy of reported treatment options for patients with metastatic CC. **METHODS:** Searches of PubMed were conducted, with no date restrictions, to identify published randomised controlled Phase II/III clinical trials (RCTs) of chemotherapies recommended by treatment guidelines, and radiotherapy and/or surgery, that reported overall survival (OS) in patients with metastatic (systemic recurrent, persistent or *de novo*-metastatic) CC. Treatment guidelines and the Cochrane Library were also explored to identify additional citations. **RESULTS:** Of 65 articles identified, 10 articles published between 1987 and 2014 proceeded to data extraction. Evidence supporting the use of chemotherapy was limited to cisplatin-monotherapy or platinum-based combination therapy. Overall the OS benefit of these agents ranged from 0.9 to 2.9 months and 0.79 to 1.32 for hazard ratio (HR). The latest innovation, bevacizumab plus chemotherapy, demonstrated the greatest significant gain in OS versus chemotherapy (OS gain 3.7 months; HR 0.71; p=0.004). The study did not identify any RCTs that supported the use of surgery and/or radiotherapy in this setting; the evidence was limited to seven retrospective hospital based studies. **CONCLUSIONS:** This study highlighted an unmet need for additional treatment options for metastatic CC. Use of cisplatin-monotherapy or platinum-based combination therapy has provided limited survival benefits for many decades. The novel combination of bevacizumab plus chemotherapy has demonstrated an increase in survival in these patients. However, since there is no RCT evidence supporting the use of surgery and/or radiotherapy, a health technology appraisal of these alternative interventions is not currently feasible. Additional clinical research is urgently needed to assess the comparative clinical value of these therapies.

PCN12

COMPARISON OF MEAN OVERALL SURVIVAL (OS) AND RADIOGRAPHIC PROGRESSION FREE SURVIVAL (RPFS) BASED ON MATCHING ADJUSTED INDIRECT COMPARISON OF ABIRATERONE ACETATE AND ENZALUTAMIDE FOR THE TREATMENT OF CASTRATION-RESISTANT PROSTATE CANCER IN CHEMOTHERAPY NAÏVE PATIENTS

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OBJECTIVES: Abiraterone acetate plus predniso(lo)ne (AA) and enzalutamide (E) are novel therapies for the treatment of metastatic castration-resistant prostate cancer in chemotherapy naïve patients. Pivotal trials have been conducted evaluating the efficacy of the drugs using different comparators. In the COU-AA-302 trial, patients were randomised between AA and active comparator predniso(lo)ne whereas in the PREVAIL trial, E was compared against placebo. For health economic purposes, the mean overall survival (OS) and radiographic progression-free survival (rPFS) of both novel agents need to be compared in the absence of head-to-head trial data. **METHODS:** Due to the difference in the comparator arms, only survival data from AA and E were used for the comparison. Observed individual level survival data with baseline patient characteristics were available for AA. Individual survival data were simulated for E to replicate the rPFS and OS curves published for the pivotal trial. rPFS and OS were modeled and extrapolated by fitting parametric survival functions. The Weibull, exponential, and lognormal models were evaluated based on statistical and clinical considerations, i.e. assessing the model fit and the implied hazard profiles, respectively. To control for differences in baseline patient characteristics (PSA, ECOG, Gleason score, BPI, LDH, metastasis, age, race) rPFS and OS estimates for AA were adjusted using a matching algorithm. **RESULTS:** The Weibull models were selected for extrapolation of both OS and rPFS. The mean rPFS was estimated to be 23.9 (95% CI: 21.5-26.3) and 19.5 (95% CI: 16.0-23.9) months for AA and E respectively. Mean OS was estimated to be 38.7 (95% CI: 36.4-40.7) and 34.6 (95% CI: 31.8-37.8) months respectively. **CONCLUSIONS:** Based on currently available data and the presented modeling approach, these findings suggest that AA is associated with longer mean rPFS and OS than E.

PCN13

CLINICAL EFFECTIVENESS OF ROBOTIC IMAGE-GUIDED STEREOTACTIC RADIOSURGERY (CYBERKNIFE) IN SELECTED PRIMARY AND SECONDARY SOFT TISSUE NEOPLASMS: A SYSTEMATIC REVIEW

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OBJECTIVES: Effectiveness of radiosurgery for head and spinal neoplasms is established. The aim of this study was to systematically review the clinical literature of CyberKnife for people with selected primary and secondary soft tissue lesions. **METHODS:** A systematic search was conducted for best available clinical data for lung metastasis, primary and secondary liver cancer, locally advanced pancreatic cancer population treated with CyberKnife radiation. Searching using Medline, EMBASE, Cochrane Library took place in September 2013. **RESULTS:** Only one relevant comparative clinical study (matched-pair analysis) met the inclusion criteria, assessing effectiveness and safety of stereotactic radiosurgery and radiofrequency ablation for colorectal liver metastasis. For other neoplasms single-arm studies were found. Compared to RFA CyberKnife for liver metastasis was significantly better in median local disease free survival, which was 34.4 months vs. 6.0 months, (p<0.001). 1 and 2-year local control rates also favored CK (85.0% vs. 65.0% and 80.0% vs. 61.0%, respectively) but the difference wasn't significant. However, trend for better OS was found with RFA (34.4 vs. 52.3 months). For lung metastasis, treatment with CK resulted in 24.0-62.0% complete or partial response, 38.0-76.0% patients stabilized. In primary liver tumors OR (CR + PR) was observed in 63.0-86.0% patients, 0.0-29.0% stabilized, median PFS reached 10.0-15.8 months. Inconsistent results were seen in locally advanced pancreatic cancer population. In one study 92.0% responded or stabilized but in other only 1 patient of 77 had PR. Median OS was 6.4-10.3 months. All studies reported mostly mild adverse events after CK. Serious AE were rare. **CONCLUSIONS:** There is limited quality evidence on the effectiveness and safety of robotic image-guided stereotactic radiosurgery in patients with soft tissue neoplasms. Available studies are highly heterogenic in methods, patients characteristics and outcomes but suggest that CyberKnife may be beneficial in local tumor control. There is a need of well-designed comparative studies.

PCN14

ANALYSIS OF TREATMENT OPTIONS FOR RELAPSED OR REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

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OBJECTIVES: For patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL), treatment outcomes are poor and treatment options are limited. Ibrutinib is an oral, once-a-day, first-in-class covalent inhibitor of Bruton's tyrosine kinase approved by the Food and Drug Administration (FDA) for R/R CLL. In a recent phase III trial (PCYC-1112), ibrutinib was associated with improved progression-free survival (PFS, hazard ratio [HR] =0.215) and overall survival (OS, HR=0.387) versus ofatumumab. The aim of this study is to provide a summary and analysis of results observed with current therapies in high-risk patients with R/R CLL. **METHODS:** A systematic literature review and targeted literature search of clinical trials and international treatment guidelines in PubMed/MEDLINE (January 1,2001–April 28,2013) and ASCO/ASH/EHA conference proceedings (2011–2013) were conducted to identify and evaluate current treatment options for R/R CLL, including alemtuzumab, rituximab, bendamustine, chlorambucil, and ofatumumab. **RESULTS:** Study results highlight poor outcomes with existing treatment options and continuously high unmet need in patients. Sixteen trials were identified; the majorities were single-arm with small sample sizes, making comparative effectiveness difficult to establish. Time-to-treatment failure was 5.8 months with alemtuzumab, while median PFS was 5.5 months with rituximab, 5.5–5.7 months with ofatumumab, 8 months with chlorambucil-ritiximab, and 15.2 months in previously-treated patients and 6.8 months in previously-treated patients with del (17p) with bendamustine-rituximab. Ofatumumab has demonstrated activity in patients with difficult-to-treat, high-risk CLL and is the only recognized and approved treatment by health authorities globally in this treatment setting and recommended in treatment guidelines. **CONCLUSIONS:** The lack of standard of care creates challenges for defining comparators in clinical trials and health technology assessments. In R/R CLL with high-risk features, ofatumumab is an appropriate comparator. Interim results from the phase III RESONATE trial showed that ibrutinib achieved significantly improved efficacy versus ofatumumab, even in high-risk disease patients.

PCN15

AN INDIRECT TREATMENT COMPARISON OF CABOZANTINIB VERSE VANDETANIB IN PROGRESSIVE MEDULLARY THYROID CANCER (MTC)

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OBJECTIVES: MTC is a rare form of thyroid cancer with prevalence of less than 7 per 100,000. A majority of MTC patients have RET mutations, and RET M918T mutations are associated with especially poor prognosis. In 2012, EMA approved the first tyrosine kinase inhibitor (TKI) CAPRELSA® (vandetanib, VDB) for the treatment of MTC. In March 2014, the EMA approved another TKI -COMETRIQ® (cabozantinib, CBZ) for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, with orphan drug status. The objective of this study was to assess the relative efficacy in PFS and OS of CBZ vs VDB. **METHODS:** Since there are no clinical trials directly comparing the two treatments, an adjusted indirect comparison (Bucher et al. method) was used. Evidence on PFS for the two treatments was collected from the pivotal clinical trials in MTC. The analysis considered all patients and a subgroup of RET M918T mutation positive (RET+) patients. Our analysis focused on PFS due to lack of evidence for the VDB OS in the RET M918T mutation subgroup. In the all patients analysis three different scenarios were explored: a logrank model to ensure comparability with the VDB data; a Cox model stratified on age at randomization and prior TKI status; and a Cox model without stratifications. **RESULTS:** In the subgroup analysis (logrank model) PFS was estimated to increase by 65% with CBZ comparing to VDB (HR 0.35; 95% CI 0.14-0.87). In the all-patients analysis the estimates were less conclusive: logrank model (HR 0.72; 0.40-1.28), Cox model with stratifications (HR 0.61; 0.35-1.04), Cox model without stratifications (HR 0.66; 0.39-1.13). **CONCLUSIONS:** The results showed a positive trend in favour of CBZ in PFS. Given the limited evidence a direct head-to-head comparison is necessary to validate the study findings.

PCN16

A SYSTEMATIC LITERATURE REVIEW TO IDENTIFY TRIALS IN FIRST-LINE RAS WILD-TYPE (WT) METASTATIC COLORECTAL CANCER (MCRC) PATIENTS

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OBJECTIVES: The aim was at assembling published evidence on treatments for RAS wild-type (wt) (KRAS and NRAS exon 2,3,4) metastatic colorectal cancer (mCRC) to evaluate the efficacy and safety of cetuximab in combination with FOLFOX or FOLFIRI chemotherapy as first line treatment of these patients. The outcomes of interest were progression free survival (PFS), overall survival (OS), overall response (ORR), and adverse event data. **METHODS:** A systematic literature search was performed on the 24th March 2014 in Medline, Embase, and The Cochrane Library to identify all randomized controlled trials (RCTs) as well as single arm trials concerning the efficacy and safety of first line interventions of interest in patients with RAS wt mCRC. Abstract and article selection was performed by two independent researchers, with a third person resolving disagreements, according to predefined standards, which were based on criteria for patient, intervention, comparator, outcomes and study design (PICOS). **RESULTS:** 596 citations were identified after removing duplicates. 520 citations were excluded for reasons including: patient population (231), study design (174), intervention (74), outcomes (23) and duplicates (18). A total of 76 abstracts were included and the full-text version of these publications were retrieved and screened resulting in excluding 69 further publications due to the study design (20), patient population (43), outcomes (5), and one (1) duplicate, not being in line with the review selection criteria. Ten citations on five different RCTs were identified that met the inclusion criteria. **CONCLUSIONS:** This systematic review provided the latest studies on RAS wild-type (wt) metastatic colorectal cancer (mCRC) treatments. Despite the small number of studies available for a relatively new biomarker-specific mCRC, anti- EGFR treatments such as cetuximab in combination with FOLFOX and FOLFIRI have demonstrated a significant benefit in progression free survival (PFS), overall survival (OS) and overall response rate (ORR) versus chemotherapy alone in mCRC RAS wt patients.

PCN20

CHARACTERISTICS OF PATIENTS WITH PLEURAL MESOTHELIOMA IN THE RUSSIAN FEDERATION

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OBJECTIVES: Malignant pleural mesothelioma (MPM) is a rare tumour with a poor survival **and** prognosis. In Russia, the epidemiology of this disease **has not been well studied**. We conducted an epidemiological study to understand the characteristics of patients with MPM in Russia. **METHODS:** Retrospective study of the characteristics of patients with MPM. Patients treated for 1st and 2ndline therapy were included in ten centers of the Russian Federation. The data were generated from hospital records, electronic databases, and other sources of information between June and December in 2013. **RESULTS:** One hundred and twelve patients were enrolled. The average age was 60.0±10.87 years and 42% were women. Harmful work environment was indicated in 21/112 (18.8%) of the patients. The exposure to asbestos was reported in 10/112 (8.9%) patients, and contact with erionite in 8/112 (7.1%) patients. Fifty percent (56/112) of the patients were smokers or are current smokers; smoking period was 25.3±13.25 years. The disease stage at diagnosis was I-II in 31 (27.6%), III-IV in 81 (72.4 %) patients. The ECOG performance status was 0 in 16 (14.3%), 1 in 46 (41.1%), 2 in 30 (26.8%), 3 in 15 (13.4%) and 4 in 1 (0.9%) patients, in 4 patients - unknown. 50/112 (44.6%) patients had immunohistochemical verification of the diagnosis. Antineoplastic drugs were used to treat 85/112 (75.9%) patients. The main drugs used were cisplatin (n=75), gemcitabine (32), doxorubicin (34), pemetrexed (29) and carboplatin (21). **CONCLUSIONS:** In Russia, the majority of MPM patients were diagnosed at advanced stages of disease. In 80% of the cases, a harmful work environment was not identified. Given the low prevalence and the frequent use of off-label medicines, it can be considered an orphan disease. Limitations: Only limited number of centres was included.

PCN21

FIRST-LINE THERAPY FOR PATIENTS WITH MULTIPLE MYELOMA: DIRECT AND INDIRECT COMPARISON OF TREATMENT REGIMENS ON THE EXISTING MARKET

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OBJECTIVES: Motivated by the discussion whether the german AMNOG is applied to currently marketed drugs we compared first-line therapies for patients with multiple myeloma (MM). **METHODS:** A systematic literature search for randomized controlled trials (RCTs) was conducted and VMP (bortezomib (Velcade), melphalan and prednisone), MPT (melphalan, prednisone and thalidomide) and MP (melphalan and prednisone) were identified as therapies of interest. We extracted information on overall survival (OS), progression-free survival (PFS), response criteria (CR, VGPR, PR), and grade 3-4 AEs (any, hematological, non-hematological, DVT, PNP). Random-effects meta-analysis was used for direct and the Bucher method for adjusted indirect treatment comparison. **RESULTS:** Seven RCTs with a total of 2,367 patients were included in our analyses, one RCT (n=682) comparing VMP vs. MP and six RCTs (n=1,685) comparing MPT vs. MP. Direct head-to-head comparison of VMP vs. MPT was lacking. For MPT vs. MP, data were extracted from a recently published meta-analysis of individual patient data if available. VMP was superior to MP regarding OS. Both VMP and MPT were superior to MP regarding PFS and response criteria, but had a higher risk of developing AEs. The indirect comparison of VMP vs. MPT via MP showed a statistically not significant advantage for VMP regarding survival outcomes. Significant benefits were observed for CR and development of any grade 3-4 AEs favouring VMP. **CONCLUSIONS:** Analysis of both aggregated and individual patient data essentially lead to the same conclusions, i.e. VMP and MPT seem more effective than MP, VMP seems ahead of MPT regarding response criteria and adverse events. We found significant between-trials heterogeneity, however no consistent relationship of effect and study-level covariates (e.g. maintenance dosing) was apparent. Thus, we relied on the random effects approach to meta-analysis to cope with the unexplained trial-to-trial variability. Our results may best be confirmed by a head-to-head trial of VMP vs. MPT.

PCN22

WHAT IS THE CLINICAL EFFECTIVENESS AND COST- EFFECTIVENESS OF ERYTHROPOIETIN-STIMULATING AGENTS FOR THE TREATMENT OF PATIENTS WITH CANCER-TREATMENT INDUCED ANAEMIA? INSIGHTS FROM CUMULATIVE META-ANALYSES (CMA) AND LESSONS FOR COST-EFFECTIVENESS ANALYSES

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OBJECTIVES: A health technology assessment (HTA) informing the recent NICE guidance regarding the use of erythropoiesis-stimulating agents (ESA) in cancer-treatment induced anaemia (CIA) identified uncertainty around the overall survival hazard ratio (OSHR). We investigated how the understanding of OS in CIA patients treated with ESAs has shaped over time and the effects of accumulating OS evidence on cost-effectiveness. In addition, the effects of narrowing inclusion criteria, by comparing the HTA results to a recent Cochrane review, were investigated. **METHODS:** CMA was applied to both HTA review and Cochrane review OS data to identify patterns in results; study results were accumulated by the year of publication. Annual OSHR results from the CMA were applied to an economic model developed in the HTA to calculate the cost-effectiveness of ESAs. **RESULTS:** Precision of the OSHR estimate appeared to improve with additional evidence, but the true location of the estimate remained uncertain and the best estimate varied over time. Using the HTA CMA, results from 2001 and 2002 suggested survival benefits to using ESAs (0.77, 95% CI 0.60–0.98 and 0.78, 95% CI 0.65–0.93 respectively), with ESAs being cost-effective at a willingness to pay threshold of £30,000 per QALY for all values of the OSHR 95% CI. HTA CMA for all other years and all Cochrane CMA results did not suggest any significant effects of ESAs on OS. Cost-effectiveness results were therefore uncertain. **CONCLUSIONS:** Current evidence suggests we cannot reject the possibility of no difference in OS between patients receiving or not receiving ESAs, regardless of study inclusion criteria. However, there is also insufficient evidence to support such conclusions, particularly as earlier results from narrower inclusion criteria suggested some survival benefits. This analysis highlights the additional uncertainty of the current evidence base on cost-effectiveness analyses, which cannot be captured in standard sensitivity analyses.

PCN23

BORTEZOMIB RE-TREATMENT IN PATIENTS WITH MULTIPLE MYELOMA (MM). A REAL WORLD MEDICAL PRACTICE EXPERIENCE FROM A SWEDISH NATIONAL REGISTRY

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OBJECTIVES: The question of sequencing multiple myeloma (MM) treatments is a key one, as is the retreatment in patients where the same treatment was effective in earlier lines. We investigated bortezomib retreatment in a Swedish MM national registry. **METHODS:** Patients diagnosed with MM since January 2000 until June 2011 from 7 university clinics, 5 regional centers and 3 local hospitals in Sweden were included. Time to response and overall survival (OS) were analyzed using stratified Kaplan-Meier analysis. **RESULTS:** Of the 541 patients treated with bortezomib (out of a total population of n=1638), 93 were retreated with bortezomib. Median follow-up from start of retreatment was 10.2 mos. Median age was 63.5 (range 38–83), 57.3% were male, 34.2%/15.9%/20.7% had stage I/II/III disease (ISS); median number of prior therapies at initial bortezomib and retreatment was 1 and 3. 26.8%/32.9% of pts initiated retreatment as 3rd/4th line therapy. 37.8%/22.0% initiated bortezomib retreatment in combination with dexamethasone, 7.3% in monotherapy, compared to 40.3%, 21.8% and 8.5%, at initial bortezomib. ≥PR/VGPR-rates at re-treatment were 59.1%/12.7%, compared to 82.0%/39.9% at initial bortezomib. Median time to ≥PR/VGPR was 2.4/1.3 months at retreatment versus 1.9/2.1 at initial bortezomib. The ≥PR rate at retreatment was numerically longer in patients with <=2 (75.1%) vs >=3 (20%) therapies prior to retreatment. Median PFS/OS from start of re-treatment was 5.5 [95%CI: 3.7, 10.0]/17.4 [10.3, 26] months, compared to 8.1 [6.9, 9.7]/25.9 months [21.0, 31.6] for initial bortezomib. Number of prior therapies at retreatment did not affect PFS; however, OS was longer in pts with fewer prior therapies (p=0.0112). There was a trend towards longer PFS (p=0.087) in retreated patients who achieved >=PR compared to non-responders. **CONCLUSIONS:** These data suggest that, in everyday medical practice, bortezomib retreatment is effective in relapsed/refractory MM, with more than half of pts who responded to initial bortezomib achieving ≥PR at retreatment.

PCN24

TREATMENT SEQUENCING SURVIVAL MODEL FOR PATIENTS WITH MULTIPLE MYELOMA INELIGIBLE FOR STEM CELL TRANSPLANTATION (SCT)

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